

SALMONELLA SAMPLING PLAN

PURPOSE:

To determine the presence of Salmonella in processed foods intended for human consumption.

APPLICABILITY

This sampling plan is applicable to the inspection of either a continuing series of production lots or to isolated lots consisting of an identifiable collection of process units (cans, bags, packages, or similar units). This plan is for use by FDA for regulatory purposes.

FOOD CATEGORIES:

Foods are listed in three categories based on the number of Salmonella hazards and whether a food is to be consumed by infants, the aged, or infirm.

The three defined Salmonella Hazards of foods are:

1. The food or an ingredient of the food is a significant potential source of Salmonella;
2. The manufacturing process does not include a controlled step that destroys Salmonella; and
3. The food has significant potential for microbiological growth if "abused" in distribution or by consumers.

Classification of Foods:

Foods have been classified into three food Categories for regulatory sampling purposes. The foods are listed in the Categories by Product Code sequence.

NOTE: For products not listed, check with your supervisor. The District will request categorization from the Office of Field Programs/Center for Food Safety and Applied Nutrition (HFS-600), or, when time is of essence, the District will make the categorization and obtain later concurrence from CFSAN.

Category I

This includes all foods that would normally be in Category II except that they are intended for consumption by the aged, the infirm, and infants.

Category II

This includes the foods that would not normally be subjected to a process lethal to Salmonella between the time of sampling and consumption. Examples are as follows:

PRODUCT FOOD ITEM

CODE

03	Bread, rolls, buns, sugared breads, crackers, custard and cream filled sweet goods
05	Breakfast cereals, ready to eat
07	Pretzels, chips and specialty items
09	Butter and butter products; pasteurized milk and raw fluid milk and fluid milk products for consumption; pasteurized and unpasteurized concentrated liquid milk products for consumption; dried milk and dried milk products for consumption
12	Cheese and Cheese products
13	Ice cream from pasteurized milk and related products that have been pasteurized; raw ice cream mix and related unpasteurized products for consumption.
14	Pasteurized and unpasteurized imitation dairy products for consumption
15	Pasteurized eggs, egg products from pasteurized eggs; unpasteurized eggs and egg products from unpasteurized eggs for consumption without further cooking
16	Canned and cured fish, vertebrates; other fish products; fresh and frozen raw oysters and raw clams, shellfish and crustacean products; smoked fish, shellfish and crustaceans for consumption
17	Unflavored gelatin
20-22	Fresh, frozen and canned fruits and juices, concentrates and nectars ; dried fruit for consumption; jams, jellies, preserves and butters
23	Nuts and nut products for consumption
26	Oils consumed directly without further processing and oleomargarine
27	Dressings and condiments (including mayonnaise) salad dressing and vinegar
28	Spices including salt; flavors and extracts
29	Soft drinks and water
30	Beverage bases
31	Coffee and tea
33	Chewing gum and candy
34	Chocolate and cocoa products
35	Pudding mixes not cooked prior to consumption, gelatin products

36	Syrups, sugars and honey
38	Soups
39	Prepared salads

Category III

This includes the following foods that would normally be subjected to a process lethal to Salmonella between the time of sampling and consumption. Examples are as follows:

02	Whole grain, processed grain and starch products for human use
04	Macaroni and noodle products
16	Fresh and frozen fish; vertebrates (except that eaten raw); fresh and frozen shellfish and crustaceans (except raw oysters and raw clams for consumption); other aquatic animals (including frog legs)
24	Fresh vegetables, frozen vegetables, dried vegetables, cured and processed vegetable products normally cooked before consumption
26	Vegetable oils, oil stock and vegetable shortening
35	Dry dessert and pudding mixes that are cooked prior to consumption
37	Frozen dinners, multiple food dinners
45-46	Food chemicals (direct additives)

SAMPLE COLLECTION

Each sub will consist of a minimum of 100 gm (approx 3.53 oz). The usual subsample is a consumer size container of a product. Subsamples should be obtained at random to insure that the total sample is representative of the lot. When a lot consists of identifiable subdivisions (e.g., different codes), sub samples should be obtained from subdivisions in the proportion that the subdivisions are to the whole lot.

More than one subsample may be collected from large institutional or bulk containers when the number of sub samples required exceeds the number of containers in the lot. A subsample will consist of more than one container when the lot consists of containers smaller than 100 gms (e.g., 4 - 25 gm containers is a subsample).

When a sample is collected by transferring it to sample containers, a sample control must be submitted which consists of an empty sample container that is exposed to the same conditions under which the sample is collected. See IOM 426.2 and 426.4 on controls. Use aseptic technique when sampling from bulk containers.

SAMPLE SIZE

The following sample sizes also apply to the finished product portion of in-line samples when analyzed for Salmonella. Each subsample will consist of at least 100 gms (approx 3.5 oz).

The number of subsamples includes the 702(b) portion.

<u>FOOD CATEGORY</u>	<u>NUMBER OF SAMPLE UNITS (SUBS)</u>
I	60
II	30
III	15

SAMPLE SUBMISSION

Submit all samples collected to your district's microbiological servicing laboratory unless directed otherwise by your supervisor or assignment. See IOM 454.2

SAMPLING SCHEDULE FOR CANNED AND ACIDIFIED FOODS

I. Canned Foods

A. Field Examination

1. Routinely examine warehouse stock for evidence of leaking cans, wet cases, swollen cans, swarms of fruit flies around isolated pallets, etc.

2. When the inspectional evidence indicates the probability of under processed lots, or lots with excessive defective units, conduct a visual examination of warehouse stock. Give preference to the examination of the lot that was processed incorrectly. However, any lot produced using the process, and preferably warehoused at least 14 days, should be examined.

3. A lot to be examined will be one production code.

4. Each field examination will consist of a maximum of 576 containers. However, a minimum of 192 containers may be examined if 3 or more abnormal containers are found.

a. Flippers. Only one end is slack or slightly bulged and the end remains flat if pressed in. Cans which bulge when sharply and squarely struck end-down on a flat surface are flippers, provided that the bulged end remains flat when pressed. Flippers result from a lack of vacuum.

b. Springers. One end of a can bulges. Manual pressure on the bulged end forces the opposite end out or the same end will spring out with release of pressure. If both ends bulge, but only one will remain flat when pressed, the can is a springer. Springers result from moderate positive pressure in the can. Buckling or extensive denting of the side wall may produce a springer.

c. Swells. Both ends of the can are bulged. Neither end will remain flat without pressure. Soft swells yield to manual pressure, but no impression can be made manually on hard swells. Swells result from positive pressure in the can usually because of spoilage of the contents. Some swells, especially in acid products, may result from chemical reaction between the contents and the container.

NOTE: Other abnormalities or defects, should be reported on C/R, but not counted as "abnormal containers" for the purposes of the sequential field examination. These other defects include visibly leaking cans, severe dents around seams, gross seam defects, severely rusted containers, etc.

5. Follow the chart on the next page for the field examination.

6. Unless the inspectional evidence of improper processing or non-compliance with the GMP's can be related to specific production lots, conduct no field examinations during the inspection. However, if inspectional evidence or other examination results indicate problems, conduct *field examinations* using the large chart on the next page for guidance.

B. Sample Size

1. Investigational

a. Samples for laboratory examination will consist of all abnormal and 12 normal containers. The sample will include as many abnormal containers as were found during your field exam (e.g., if 21 abnormal containers are observed during the examination, the sample will consist of 21 abnormal and 12 normal containers). Do not collect leakers, but report the number noted.

It may be necessary to collect samples of any other defects noted such as seam defects to support observations and document the severity of the defects. In some cases, photographs may be a suitable substitute for collection of physical subsamples.

a. Report the results of the field examination in the EIR and as a Field Exam in FACTS. If a sample is collected, on the C/R. Identify, by sub-sample number, the condition of each container in the sample (e.g., sub-sample 1 - flipper; sub-sample 2 - hard swell; -----sub-sample x – normal).

UNCASED CONTAINERS		PACKED 48/CASE		PACKED 24/CASE		PACKED 12/CASE		PACKED 6/CASE		
LOT SZ CONTAIN.	NO. TO EXAMINE	LOT SIZE (CASES)	CASES TO EXAMIN E	LOT SIZE (CASES)	CASES TO EXAMIN E	LOT SIZE (CASES)	CASES TO EXAMINE	LOT SIZE (CASES)	CASES TO EXAMINE	NUMBER ABNORMAL CONTAINER S TO DISCONTIN
192 or less	all	1 - 4	all	1 - 8	all	1 - 16	all	1 - 32	all	3
193 - 288	192	4 - 6	4	8 - 12	8	16 - 24	16	32 - 48	32	5
289 - 384	all - 298	6 - 8	6	12 - 16	12	24 - 32	25	48 - 64	all - 50	6
385 - 576	363	8 - 12	8	16 - 24	15	32 - 48	30	64 - 96	61	7
577 - 912	433	12 - 19	9	24 - 38	18	48 - 76	36	96 - 152	72	8
913 - 1488	480	19 - 31	10	38 - 62	20	76 - 124	40	152 - 248	80	9
1489 - 3408	529	31 - 71	11	62 - 142	22	124 - 284	44	248 - 568	88	10
3409 or more	576	71 or more	12	142 or more	24	284 or more	48	568 or more	96	11

*For a given lot size, when the specified number of abnormal containers is found, discontinue the examination and collect the abnormals ONE NORMAL CONTAINER TAKEN FROM EACH OF 12 CASES. Open additional cases, if necessary, to meet this requirement. When the maximum number of containers/cases have been examined, always collect a sample as directed above, if one or more abnormal containers have been found. IT IS ABSOLUTELY NECESSARY TO INCLUDE ON THE COLLECTION REPORT THE LOT SIZE, THE NUMBER CONTAINERS EXAMINED, AND THE NUMBER OF ABNORMAL CONTAINERS FOUND BY TYPE (E.G., HARD SWELLS)

2.Official

NOTE: Products in 55 gallon drums, or similar large containers, either aseptically filled or heat processed should not be sampled while the shipment is enroute unless the owner accepts responsibility for the portion remaining in the opened containers. Arrange sampling of these products at the consignee (user) so the remaining portion can be immediately used or stored under refrigeration. Always use ASEPTIC TECHNIQUE when sampling these types of products.

A lot is defined as one production code.

a.Filth, Micro, etc. (Includes 702(b) portion)

Collect each subdivision in duplicate from a separate case, if possible. Mark subs 1a, 1b, 2a, 2b, etc. Collect as follows:

	Size of Lot	Min total	Cans/case
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		cans	
906 gm (2 lbs.) Net weight and smaller	Up to 50 cases	48	2 from 24
	More than 50 cases	96	2 from 48
Over 906 gm (2 lbs)	Up to 600 cases	48	2 from 24
	More than 600 cases	72	2 from 36

b. Standards Assay (Includes 702(b) portion)

NOTE: Sample sizes listed below are based upon the requirements of the Standards (21 CFR 145.3)

When sampling products, which are likely to be non-uniform throughout the lot because of variations from standards of quality, identity, fill-of-container, grade, etc., collect each subdivision in the triplicate from a separate case. Mark subs 1a, 1b, 1c, 2a, 2b, 2c, etc. Collect as follows:

	Number of cans or packages	Min total cans	Cans/case
1 kg (2.2 lbs) Net weight or less	4800 or less	48	3 from 16
	4801 to 24,000	72	3 from 24
	24,001 to 48,000	96	3 from 32
	48,001 to 84,000	144	3 from 48
	84,001 to 144,000	264	3 from 88
	144,001 to 240,000	384	3 from 128
	Over 240,000	600	3 from 200
Greater than 1 kg (2.2lbs), but less than 4.5 kg (10 lbs.)	2400 or less	48	3 from 16
	2401 to 15000	72	3 from 24
	15001 to 24000	96	3 from 32
	24001 to 42000	144	3 from 48
	42001 to 72000	252	3 from 88
	72001 to 120,000	384	3 from 128
	Over 120,000	600	3 from 200
Greater than 4.5 kg (10 lbs)	600 or less	48	3 from 16
	601 to 2000	72	3 from 24
	2001 to 7200	96	3 from 32
	7201 to 15000	144	3 from 48
	15001 to 24000	252	3 from 88
	24001 to 42000	384	3 from 128
	Over 42000	600	3 from 200

3. Acidified Foods(Metal or Glass)

A lot is defined as one production code.

Samples must be collected randomly from the entire lot. **Sample size does not include 702(b) portion.**

10 size containers – Randomly select 1 normal container from each of 12 randomly selected cases (if available) in the lot.

2 ½ and smaller –Randomly select 2 normal containers from each of 12 randomly selected cases (if available) in the lot. Sample size is 24 containers.

For acidified products, the equilibrium pH determines whether the product will support organisms of public health significance. Spoilage in such products is usually due to inadequate heat treatment to kill spoilage organisms. When abnormal containers of acidified products are found during domestic plant inspections, the Investigator should determine the cause of spoilage through inspectional observations and/or record review. It will not ordinarily be necessary to collect samples of abnormal containers of domestic acidified products, unless the reason for the abnormality has potential health hazard significance; the reason cannot be determined; or , the lot contains 1% or more abnormal containers and is intended for shipment or has already been partially shipped. However, since inspectional follow-up is not practical for imported acidified products, always collect abnormal containers to serve as a basis for determining progressive decomposition or product adulteration.

When collection of abnormal containers is indicated, conduct an examination following the sequential plan provided for canned foods. Collect all abnormal containers (up to a maximum of 24) in addition to the normal containers collected for pH determination. Indicate on the C/R the total number of containers examined and the number of each type of abnormality and defect observed. Also indicate the estimated percentage of abnormal containers in the lot.

PESTICIDE SAMPLES

(Includes 702(b) portion)

DO NOT FUMIGATE PESTICIDE SAMPLES**INTRODUCTION**

The objectives of FDA's pesticide monitoring program are to gather information on levels and incidence of pesticide residues in the nation's food supply and to initiate enforcement action against shipments of food and feed found to contain illegal pesticide residues. To meet both objectives, it is necessary to collect samples of food and feed for pesticide residue analysis. These instructions describe procedures for collecting samples of raw agricultural commodities and processed commodities. The procedures apply to domestic and import shipments. The instructions include a separate set of procedures for collecting samples for special investigations such as determining levels of pesticide residues in soil, water, and growing crops.

Pesticide sample sizes no longer differentiate between Surveillance and Compliance Samples. All pesticide samples will be collected as directed below. Remember to include the state and county or country of origin in the Flag. See IOM 439.1.

For appraisal purposes, you must Flag each Domestic and Import Sample as to the basis for sampling in accordance with the definitions below.

Pesticide Compliance Sample. Collected on a selective basis as a result of inspectional or other evidence of suspected misuse of a pesticide on a food or feed commodity or as a follow-up to a "Pesticide Surveillance Sample" that was found to contain actionable levels of pesticide residues. Flag "Pesticide Compliance".

Pesticide Surveillance Sample. Collected on an objective basis where there is no evidence or suspicion of pesticide misuse on a food or feed commodity. Flag "Pesticide Surveillance".

1. GENERAL SAMPLING INSTRUCTIONS

SAMPLE SIZES FURNISHED IN THIS SCHEDULE APPLY TO BOTH DOMESTIC AND IMPORTED FOOD AND FEED COMMODITIES.

<u>GENERAL SAMPLING SCHEDULE</u>		
Lot Size (Cases Crates, boxes, etc)	No. 900 gm (2 lb) subs	Total Sample Size kg (lbs)
12 or less	5	4.5 kg (10)
13 to 18	6	5.4 kg (12)
19 to 30	7	6.3 kg (14)
31 to 56	8	7.3 kg (16)
57 to 190	9	8.2 kg (18)
over 190	10	9.0 kg (20)

Unless instructed otherwise minimum sub size will be 900 gms (2 lbs).

2. FRESH PRODUCE

Districts have the option to collect 1 intact shipping case [minimum of 9 kg (20 lbs)] or a total of 9 kg (20 lbs) from one or more large containers of fresh produce from packing sheds or large produce warehouses. This "one case" option may be used on domestic Pesticide Surveillance Samples, if the collector can be assured that the "one case" collected is representative of the lot or field. If the collector is not assured of this, collect the samples as indicated in the General Sampling Schedule above. This "one case" sampling does not apply to large items such as melons.

NOTE:

If "one case" option is used for surveillance samples of domestic produce, describe in the Remarks Section of the CR, the basis for determining that the sample is representative of the lot or field.

ALL SURVEILLANCE SAMPLES OF FRESH IMPORTED PRODUCE, EXCEPT GRAPES FOR SULFITES, WILL CONSIST OF ONE CASE, BAG, BALE, BOX, ETC.

3. GRAPES FOR SULFITES

Collect approximately 900 - 1800 gms (2 - 4 lbs) of grapes [10/100 - 200 gm (1/4 to 1/2 lb) subs]. Each subsample will consist of individual grapes, not bunches, and will be collected from different lugs (cases) on as many different pallets in the lot as possible. No grapes that are damaged during the sampling procedure should be included in the sample. However, grapes with damage prior to sampling may be included in the sample.

If sulfiting pads are present, grapes sampled should be selected from areas closest to and directly under the pad.

Monitoring activities should be focused upon lots of grapes with the highest potential for violative sulfite residues.

Direct efforts to lots of grapes sulfited through fumigation or to lots with multiple fumigations especially towards the end of the harvesting season and also to lots with significant numbers of damaged grapes (split, crushed, or unusually wet, if such damage is apparent).

Sample lots of grapes sulfited through use of sulfiting pads, with or without additional fumigation. If at all possible, sample lots subjected to the following conditions, which could cause high sulfite residues:

Lots subjected to unrefrigerated storage of 2 or more hours during warm weather.

Unusual shipping conditions (ships at seas during heavy storms.

Lots with significant numbers of damaged grapes.

Lots containing evidence of sulfite pad damage sufficient to cause spilling of sulfiting agent onto grapes.

Special Sample Handling

Place sample in tightly closed airtight glass mason jar(s) or sealed plastic bag(s). Although no effort should be made to commingle subsamples, more than one subsample may be placed in the same container for shipping convenience.

Appropriate cooling procedures are:

Place samples in shipping container or cooler with sufficient ice or other refrigerant to keep sample refrigerated until arrival at the laboratory. Sample should be placed immediately in a refrigerator at or below 7°C. If sample is not to be analyzed within a few hours, the sample should be placed in a freezer, which is maintained at or below -20°C.

or

Place sample in container with sufficient dry ice to keep sample frozen until arrival at the lab, sample should be placed in freezer upon arrival at laboratory.

4. FLUID MILK PRODUCTS

Retail Containers

Use General Sample Schedule. Sub size will be 1 retail unit (1 pt, 1 qt, 1/2 gal, etc.). When the retail container is less than 16 ozs, collect 2 units per sub.

Bulk Tank Trucks

Collect two (2) qts from each bulk tank after agitation.

5. MANUFACTURED DAIRY PRODUCTS

Concentrated Liquid Milk Products

Use General Sample Schedule. Subsample size will be 1 retail unit. If retail unit container size is less than 16 ozs, collect 2 retail units per sub.

Dried Milk Products, Cheese, Ice Cream, and Related Dairy Products

Use General Sample Schedule, using the following subsample sizes:

<u>Container Size</u>	<u>Minimum Units Per Sub</u>
Less than 16 oz (pt)	2
Over 1 pint	1
Less than 453 gms (1 lb)	2
453 gms (1 lb) thru 10.9 kg (24 lbs)	1
11.4 kg (25 lbs) or more in bags or drums.	453 gm (1 lb) From each unit
Use Aseptic Technique	sampled

6. EGGS AND EGG PRODUCTS

Liquid or Frozen Eggs

Use General Sample Schedule. Subsample size will be 1 pt liquid or 1 qt packed shavings from drillings. Subs will be collected using aseptic technique.

Dried Egg Products

Use General Sample Schedule. Use same sub sizes as in 4.b. Dried Milk Products. Use Aseptic Technique.

Shell Eggs

Retail Packages (1 doz.) - Use General Sample Schedule - Sub size 1 dozen

Commercial Cases

15 cases or less - 1 dozen from each case, minimum 2 dozen - maximum 10 dozen

16 cases or more - 1 dozen from each of 10 random cases

Grower Samples or lots that can be identified to a specific grower - 6 dozen

7. FISH AND SHELLFISH PRODUCTS

NOTE: THIS SAMPLE SIZE FURNISHES SUFFICIENT FISH FOR HEAVY METAL ANALYSIS.

Packaged Fish, fresh, frozen, smoked, cured, or shellfish (except oysters)

Collect 12 subs - minimum sub size is 453 gms (1 lb)

Bulk Fish - .453 - 1.35 kg (1 - 3 lb)/fish

Collect 12 subs, each sub to consist of 453 gm (1 lb) of edible fish

Bulk Shellfish (except oysters)

Collect 12 - 453 gm (1 lb) subs

Canned Fish and Shellfish Products (except oysters)

Collect 12 subs - 5 cans per sub

Other Fish and Shellfish Products

Oysters - Collect 12 1 pint subs

Fish Flour and Meal

Use Compliance Sample Schedule. For containers 11.4 kg (25 lbs) or larger, collect 900 gms (2 lbs) per sub

SWORDFISH FOR HEAVY METALS

These sample sizes **must** be used whenever sampling swordfish, either for audit, surveillance, or compliance purposes.

Whole Fish (dressed, head removed)

Characterize lot in terms of fish sizes, i.e., small, medium, and large. The following dressed weight ranges are used for classification:

Small Fish - Weighs less than 36.4 kg (80 lbs)

Medium Fish - Weighs 36.4 - 54.5 kg (80 - 120 lbs)

Large Fish - Weighs more than 54.5 kg (120 lbs)

For lots consisting of 12 or more fish, the representative sample to be collected will be determined by the following formula:

$$ns = (n) (Ns) / N$$

ns = the number of fish in a given weight range from which subsamples must be taken

n = total number of subsamples to be collected from the lot. (In using this formula n will always equal 12)

Ns = the number of fish in a given weight range in the lot

N = the total number of fish in the lot

Example: If a lot consists of 25 fish and is characterized as: 5 small fish [less than 36.4 kg(80 lbs)], 15 medium fish [36.4 - 54.5 kg (80 - 120 lbs)], and 5 large fish [greater than 54.5 kg (129 lbs)], the sample should be collected as follows:

$$\text{small fish} \quad \frac{(12)(5)}{25} = 2.4 = 2$$

$$\text{medium fish} \quad \frac{(12)(15)}{25} = 7.2 = 7$$

$$\text{Large fish} \quad \frac{(12)(5)}{25} = 2.4 = 2$$

TOTAL SAMPLE: 11 sub samples

Usually, the total sample will consist of 12 subsamples. However, due to rounding numbers of subsamples determined by the formula may be 11 or 13 in some instances. The total sample should consist of the specific number of sub samples determined by the formula in all cases.

Each sub sample should consist of approximately a .453 kg (1 lb) steak cut from just below the nape of the fish. Care should be taken to avoid mutilation of fish. The individual fish from which the private laboratory takes the sub sample should be identified with a tag or other suitable method. This will permit FDA to take audit samples from the same fish sampled by the private laboratories.

For lots consisting of 12 or less fish, collect 1 sub from each fish.

Swordfish Loins (slabs or sides cut from dressed whole fish which has been boned or trimmed).

Use the same formula stipulated for whole fish, with the exception that the following weight ranges should be used to characterize the lot:

Small fish loins = weighs 9.1 - 18.2 kg (20 - 40 lbs)

Medium fish loins = weighs 18.2 - 36.4 kg
(40 - 80 lbs)

Large fish loins = weighs over 36.4 kg (80 lbs)

Swordfish Steaks

Collect 12 sub samples, i.e., 12 steaks, at random from different containers in the lot (as many as possible)

Canned Swordfish

Collect 12/453 gm (1 lb) sub samples at random

8. RETAIL CONTAINERS CANNED, FROZEN AND DRIED FOODS

Use General Sample Schedule - Sub size is 900 gms (2 lbs)

9. GRAINS AND FLOUR FOR HUMAN USE

Use General Sample Schedule. For containers 11.4 (25 lbs) or larger take 900 kg (2 lbs) per sub

10. HAY, FEEDS, SILAGE, AND BY-PRODUCTS FOR ANIMAL FEED

Use General Sample Schedule. Collect 900 gm (2 lbs) per sub. When sampling from bulk, collect 10 - 900 gm (2 lb) subs to yield a 9.1 kg (20 lb) sample.

11. SPECIAL INVESTIGATIONS

Growing Crops

Superimpose an imaginary grid on the field dividing it into approximately 100 areas. Randomly select 10 areas to form a representative sample of the field. Collect one pound subs from each area. Combine to form a composite. If a sample is being collected to document drift, etc. **DO NOT** composite subs. In addition, diagram the field in the Remarks Section of the C/R and indicate sub number where each sub was collected.

For leafy vegetables, such as lettuce, cabbage, etc. INV Samples collected in the growing field should be representative of local commercial harvesting practices. If the local practice is to strip outer leaves at the time of harvest, this practice should be followed when collecting field samples. In head lettuce, for example, the lettuce may be packed directly into shipping cartons in the field, in which case 6 or 8 outer leaves are left on the head to be removed at the retail outlet. In other instances, each head is stripped of 2 or 3 outer leaves and individually wrapped in plastic, placed in shipping cartons, and the consumer receives the produce in this condition. Describe sampling method on C/R and describe how packing shed handles produce prior to shipping (e.g., washing, waxing, stripping, etc.).

Soil Samples

Collect soil samples from fields according to the following 3x3 grid diagram:

a

b

c

1	o	o	o
2	o	o	o
3	o	o	o

Sample at the 9 locations indicated by the "o". If the field being sampled is very large, you may have to sample it using a 4x4, 5x5, or even larger grid pattern.

Subs are to be placed in clean quart glass jars, which have been washed in water, rinsed in methanol, and air dried. If methanol is not available, use washed, air dried jars and submit an empty jar as a control. Note on CR that jars were or were not rinsed with methanol.

Obtain two "6 in" deep plugs (1-2 in. in diameter from each sampling location. Place two plugs from each location in cleaned glass jars, place clean aluminum foil over top of jar and seal with screw cap.

Soil samples should be submitted to the lab at 4°C (39°F) or below.

Water Samples - Collect 3 quarts of water from the same sampling source (e.g., faucet, stream, lake, etc.) and place in cleaned, washed and methanol rinsed jars as described under "Soil Samples".

Submit water samples to lab at 4°C (39°F) or below.

GENERAL

Official Samples **shall** be collected whenever feasible unless they are not required to accomplish the objective of the assignment. Investigational Samples **shall** be collected only when Official Samples are not readily available.

See IOM Sample Schedule Chart 4, Wheat Carload Sampling for guidance in the collection of samples by trier from railcars and trucks.

Consult with your supervisor in cases of doubt as to sample cost, size, or collection technique.

When collecting samples in glass jars, line the lids with aluminum foil which has been certified by the laboratory as contaminant free or use teflon lined lids.

If shipment of shell eggs is required and breakage may result during transit, subs may be broken, shells discarded, and liquid magma collected in clean glass jars. Each sub jar should be properly identified.

Samples collected at Packing Sheds should be representative of the produce as shipped in commerce. DO NOT strip outer leaves from subs collected at packing sheds from bulk lots, shipping cartons ready for shipment, intransit lots or at final destination. If the packing shed practice is to strip outer leaves prior to shipment, follow this practice when collecting the samples. Describe the sampling method on the C/R.

DO NOT USE magic markers, etc. to identify sub bags, because the ink may affect assay results. Use stick on labels to identify sub bags.

Collect samples in the container in which the dealer is packaging the product. If the dealer is packaging the product in plastic bags, collect sample in these bags. If the firm is not packing the product, collect the samples in paper bags, cardboard cartons, etc. Do not use plastic bags as this may interfere with the analysis, unless the bags are certified as contaminant free by your district laboratory.

Samples must be delivered as promptly as possible to the laboratory if regulatory action is to be taken against actionable lots.

Hold samples in cold storage until ready to be shipped or delivered to the laboratory only if normally held or shipped under refrigeration in commercial practice.

Use aseptic technique, where applicable, when collecting samples of finished products from bulk containers.

If the "one case" option is used to sample domestic fresh produce from a lot or field, report in the Remarks Section of the C/R, the facts used to determine that the one case is representative of that lot or field.

REMEMBER SURVEILLANCE SAMPLES OF IMPORTED FRESH PRODUCE, EXCEPT FOR SAMPLES OF GRAPES FOR SULFITES, SHOULD BE ONE CASE.

WHEAT CARLOAD SAMPLINGI. SAMPLING NORMAL CARS

CAUTION: WHEN USING A GRAIN PROBE, BE CAREFUL NOT TO CLOSE THE TRIER COMPARTMENT DOORS ON YOUR FINGERS.

Collect samples only of specific assignment.

A. Equipment

1. Double tube compartmented trier, 60 in. long
2. Sampling cloth at least 60 in. long
3. 1000 ml plastic graduate
4. Paper bags or other suitable containers capable of holding more than one quart of sample and **do not** use canvas bags.
5. Fumigant, chloroform or paradichlorobenzene (mothballs)
6. Absorbent cotton or equivalent
7. FDA Metal Car Seals for resealing railroad cars
8. Aluminum ladder
9. Block and tackle to open railcar door

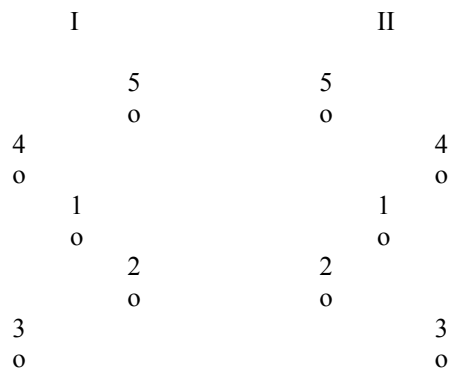
B. Drawing Sample

Principal sources of grain samples are railcars, barges, and trucks. Draw 5 probes (in duplicate) for each sample taken as described below. However, if the sample is to be Field Examined, an initial sample of 5 probes drawn as indicated below will be sufficient.

Probe samples from railcars and trucks as follows:

1. Probe #1 - From Center of car
2. Probe #2 - From 3-5 feet back from door post toward end of the car and approximately 2 feet from the side of the car.
3. Probe #3 - From 3-5 feet from the same end of the car, but approximately 2 feet from the opposite side of car as Probe #2.
4. Probe #4 - Same as Probe #2, but opposite end of car.
5. Probe #5 - Same as Probe #3, but opposite end of car.

Sketches I and II below are alternatives showing the approximate sampling locations.



Insert trier in the grain at an angle of about 10° from the vertical, with the slot up and closed. Open slots, give trier 2 or 3 short up and down motions, so that the openings will fill. Close slots (SEE CAUTION AT BEGINNING OF SCHEDULE), withdraw trier and carefully empty over sampling cloth. The cloth should be long enough to catch product from each compartment separately when you open the trier compartment doors; e.g. about 6 feet long.

C. Field Examination

Examine each pocket of the probe separately, looking for evidence of pink wheat, rodent pellets, insect damage and uneven loading or plugging. Note any insect infestation and record types of insects and whether live or dead. Count and report for each probe the number of rodent pellets, or rodent pellet fragments. Follow procedure in I.C.2 below. Count as pellets any that are sufficiently large to be readily identified by size, shape, surface coating, and/or presence of rodent hairs. Report the number of rodent pellets per sub. Measure the volume of each sub (probe) in quarts and calculate the average number of pellets per quart per I.C.2.a below. Place pellets from each sub in separate vials and submit with each wheat sub. Place each of the wheat subs in clean, suitable containers such as ice cream cartons or temporarily in clean paper bags.

Do not use canvas bags or take glass jars into railcars.

Substantially larger loads will require additional probing or larger samples taken from falling grain during loading or unloading operations.

Submit all suspect samples to laboratory for confirmatory analysis.

1. Non-Violative Samples. When field examination shows sample as non-violative, return grain to the car, unless collected for pesticide analysis. Report results in the Remarks Section of the C/R.

2. Violative Samples

- a. Rodent Pellet Contamination. The guideline for determining whether wheat is violative due to rodent contamination is: "9 mg or more rodent excreta pellets and/or fragments of rodent excreta pellets per kg of wheat."

NOTE: Since it is impractical to weigh rodent pellets and wheat in the field, the following estimations can be used. Mouse pellets average approximately 8.7 mg each and a kilogram of wheat about 2.35 pints. This translates roughly as 1 pellet per quart of wheat or 1/2 pellet per pint.

Where your field examination reveals one or more rodent pellets (or you can estimate that sufficient fragments of rodent pellets exist to equal one pellet) in a quart of wheat, take duplicate probes to furnish the claimants portion. Take the duplicate probes from the same locations as the original probes. Place the duplicates in separate containers and identify these to correspond with the original probes.

- b. Pink Wheat. Where evidence of pink wheat or other fungicide treated wheat is found, collect 15 probe samples. Take 5 probes from each end of the car and 5 probes from the center of the car. Submit the three 5-probe portions separately, using new clean containers.
 - c. Insect Damaged Kernels. The violative status of these samples should be established by laboratory analysis. When any evidence of insect damage is revealed by cursory examination, collect duplicate samples and submit for laboratory analysis.
3. Resealing Cars See IOM 424.2.
 4. Procedures for Actionable Cars. If field examination reveals an average of one or more rodent pellets per quart or gross evidence of insect-damaged kernels, evidence of plugging, or "pink wheat" contamination, determine any movement of the car or other disposition of the grain and notify your supervisor immediately.
 5. Preparation of Sample for Laboratory Analysis. If a sample can be delivered to the laboratory promptly and confirmatory analysis handled expeditiously, fumigation of the FDA probes is not necessary. The claimant's portion of the sample, however, must be fumigated. Otherwise fumigate all probes with chloroform or other suitable fumigant. Use about 5 ml per pint of wheat if transferred to glass jars. If in ice cream-type containers, use at least 10 ml. **DO NOT** pour fumigant directly on the grain, saturate a piece of absorbent cotton or blotting paper with the fumigant and add to each container. Label to show sample as fumigated and include name of fumigant on label. Officially seal all probes. Keep upright so that fumigant vapors will migrate down through the grain.

- D. Special Reporting

Submit an Analyst Worksheet (FDA-431) for each sample analyzed and found in compliance. See IOM 427.1

If field examination shows the sample is possibly actionable, report analytical results in Remarks Section of the C/R.

- II. SAMPLING PLUGGED CAR

If uneven loading, layering or "plugging" is suspected, contact your supervisor as to whether to sample or not. A "plugged" car is a railcar, truck, or barge load of grain where the contamination is suspected of being in only one portion or layer of grain. Plugging is usually the deliberate mixing of violative grain below the surface or in isolated pockets of grain.

- A. Equipment

Equipment needed is the same as in 1.A. above except:

1. Double tube grain probe must have individual compartments permanently separated.
2. Small containers of sufficient size to hold the contents of each compartment of each grain probe.

- B. Procedure

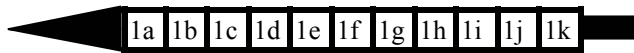
1. In the Remarks Section of the C/R, draw a diagram showing actual "plugging" pattern suspected.

2. Each sample consists of thirty probes of grain with each probe compartment maintained as a separate sub. Each sample thus consists of 300-330 subs depending on whether a 10 or 11 compartment probe is used and if grain depth is sufficient to insert the probe to fully cover all compartments of the probe.
3. Probe each load and number the probes as follows:

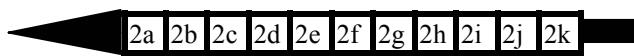
1 4 7 10 13 16 19 22 25 28
2 5 8 11 14 17 20 23 26 29
3 6 9 12 15 18 21 24 27 30

4. Identify the subs by probe number plus compartment letter starting with small "a" as the compartment nearest the tip of the probe.

Example:



Probe #1



Probe #2

4. Submit sample to your district's servicing laboratory. See IOM 454.2.

IMPORTED WHITEFISH SAMPLING SCHEDULE

GENERAL

This Sample Schedule objective is to maintain import lot integrity from time of importation thru FDA inspection or examination and final action.

Shipments will be special manifested from non-lab ports to DO cities and other cities designated by the DD as FDA inspection points. These shipments will arrive in Customs bonded trucks under seal applied by Customs at the port of entry. Customs Entry documents and commercial invoice will accompany each shipment. The commercial invoice contains a description of the lots in the shipment and will serve as a guide in the selection of the lots to be sampled.

1. Special Manifested Shipments:

- a. Determine if seals are intact and record seal number.
- b. FDA metal seals may be broken and lots checked against invoice.
- c. Customs seals may be broken only if authorized by Customs.
- d. Lots which are not to be examined will be released by completing the "MAY PROCEED" block of the FDA-701.
- e. Sample lots to be examined by using either the Single or Sequential Sampling Plan depending on whether examination is made at the DO Lab or at the dock. The Sequential Plan can only be used where additional fish are immediately available for cutting.

2. Definition of a Lot & Selection for Examination.

- a. A lot is defined as "Each group of fish of a distinct size, listed in the invoice as from a distinct lake, will be considered as a separate lot. Where an invoice does not list lakes of origin of boxes of fish in a shipment, fish of the same size and kind will be considered to comprise a single lot. When the size of the fish or lakes of origin in a shipment are not specified, the shipment will be treated as a single lot."
- b. Limit sampling to lots containing 5 or more boxes unless deliberate splitting up of lots is suspected.
- c. Basis for Sampling. Select lots for sampling on either a "selective" or "objective" (random) basis. The criteria in selective sampling may be prior knowledge or suspicion that fish listed as from a given lake are likely to have excess cysts; that the shipper has been known to manipulate shipments; etc. Regardless of the reason for selective sampling, record the basis for sampling each lot in your examination report. Simply list the basis as "selective" or "objective" next to the results of each lot sampled.
- d. Normally, select boxes in a lot for sampling at random. However, where there's evidence of layering, selectively sample the suspect boxes.

3. Sampling Schedule.

a. Imported samples of whitefish & related fish for parasites. The sampling schedules estimate lot quality more precisely, thereby reducing the likelihood of passing a lot which should be detained, or vice versa, due to an inadequate sample.

SCHEDULE A below is a single sample plan for use in collecting samples for examination in the district lab or other location where it is impossible or undesirable to return and obtain additional fish.

SCHEDULE B below contains sequential sampling plans for use when the exam is made at a customs office or a carrier's dock where you have immediate access to the lot and can obtain additional fish, if necessary.

The sequential plan for lots of 20 to 100 boxes is presented in tabular form. the sequential sample plan for lots of 100 or more boxes is presented in a sampling chart. For small lots of 5-20 boxes, a sequential sample plan is not feasible. All import sampling plans are based on lot size and the sizes of the fish in the lot.

When lots are very good or very poor quality, in terms of cyst infestation, double sample plans require a smaller sample size on the average than single sampling plans, to reach a decision.

b. Domestic Samples for Parasites.

1. For Laboratory Examination.

Lots of 11 or more boxes; Collect at least 25 fish from a representative number of boxes.

For small lots, under 11 boxes; Collect 12 fish from a representative number of boxes.

2. For Examination in Other Than Laboratory.

Cut a preliminary sample in accordance with the appropriate double sampling plan, Schedule B. Cut the additional sample where indicated or bring the additional sample to the laboratory for examination.

Number of Boxes in Lots	NUMBER OF KG'S (POUNDS) IN A SAMPLE <u>1</u> /		
	Jumbo or Large <u>2</u> /	Medium <u>2</u> /	Small <u>2</u> /
5 - 19 boxes	12.7 Kg (28lbs)	10.5 Kg (23lbs)	7.3 Kg (16lbs)
20 - 100 boxes	24 Kg (73lbs)	20.5 Kg (45lbs)	15 Kg (33lbs)
100 or over	32 Kg (70lbs)	25.5 Kg (56lbs)	17.8 Kg (39lbs)

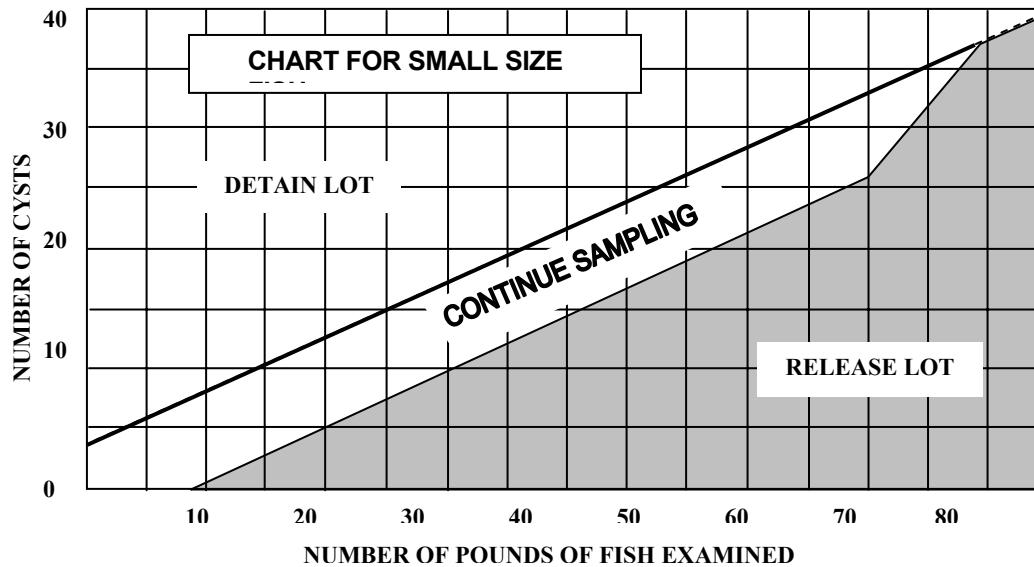
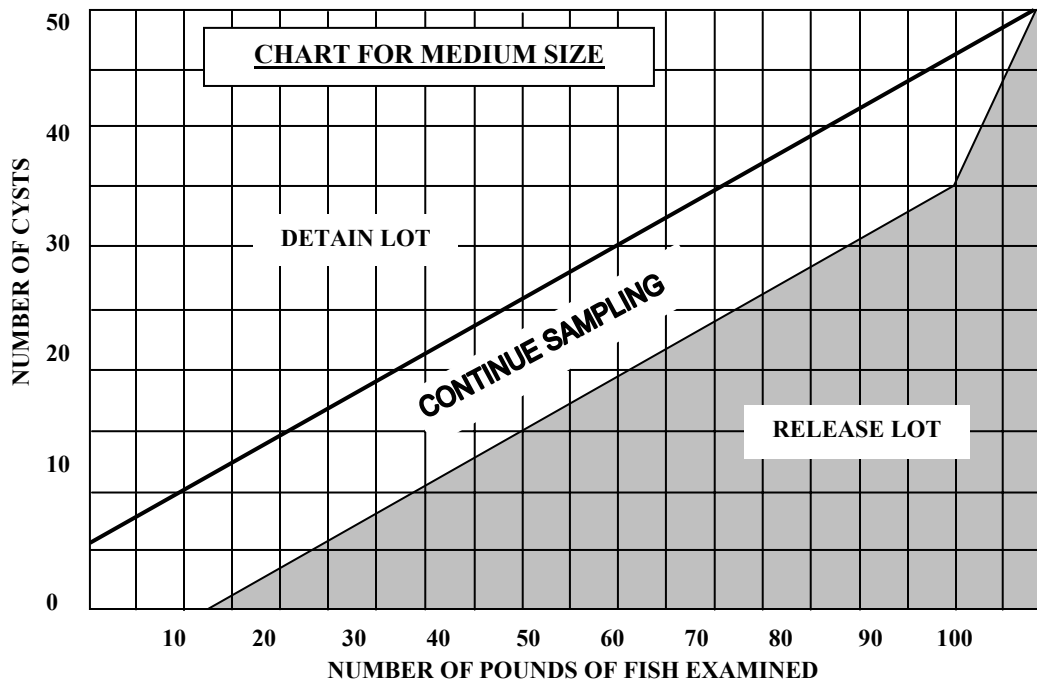
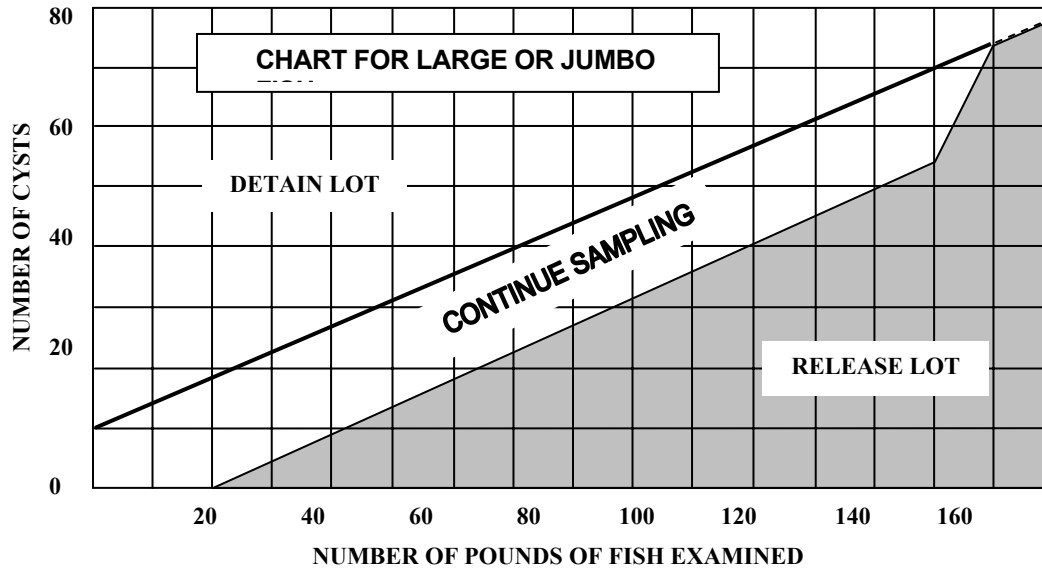
SMALL	Under 675 gms (1 1/2lbs)
MEDIUM	675 gms (1 1/2lbs) & under 1.4 Kg (3lbs)
LARGE	1.4 Kg (3lbs) & under 1.8 Kg (4lbs)
JUMBO	Over 1.8 Kg (4lbs)

SCHEDULE B - SEQUENTIAL SAMPLE PLAN							
1. <u>Limited to lots of 20 - 100 boxes.</u> 454 Kg (1000lbs) to 2272 Kg (5000lbs)							
Size of Fish <u>1/</u>	Size of preliminary Sample	Cysts/45.5 Kg (100lbs) in Preliminary Sample			Size of ADD'L SMPL	Cysts/45.5 Kg (100lbs) in sample	
		PASS	DETAIN	TAKE ADD'L SMPL		PASS	DETAIN
Large & Jumbo	16 Kg (35lbs)	30 or less	70 or more	31-69	28.6Kg (63lbs)	49 or less	50 or more
Medium	12.3 Kg (27lbs)	26 or less	67 or more	27-66	19.5 Kg (43lbs)	49 or less	50 or more
Small	8.2 Kg (18lbs)	38 or less	61 or more	39-61	11.8Kg (26lbs)	49 or less	50 or more

1/ When an invoice does not designate the size of the fish in the shipment and inspection reveals more than one size in the lot, use sampling plan for medium fish.

2/ For lots of 100 boxes or over, use the Sequential Sampling Chart for the particular size fish in the lot.

WHITEFISH SEQUENTIAL SAMPLING PLAN (WHEN LOT SIZE EXCEEDS 100 BOXES)



MYCOTOXIN SAMPLE SIZES

PRODUCT SAMPLE SIZES FOR MYCOTOXIN ANALYSIS

(Includes 702(b) portion - each sample unit, contains product for the reserve portion, no duplicate subs are necessary)

NOTE: COMPLIANCE SAMPLE SIZES MAY DIFFER FROM SURVEILLANCE SAMPLE SIZES.

PRODUCT	PACKAGE TYPE	LOT SIZE	NUMBER OF SAMPLE UNITS*	UNIT SIZE (minimum)	TOTAL SAMPLE SIZE (minimum)
Peanut Butter (smooth)	Consumer or bulk	NA	24	225 gm (8 oz)	5.4 Kg (12 lbs)
			12	454 gm (1 lb)	5.4 kg (12 lbs)
Peanut Butter (Crunchy) Peanuts shelled roasted, or unroasted, Peanuts ground for topping	Consumer or bulk	NA	<u>INITIAL SAMPLE</u>		
			10	454 gm (1 lb)	4.5 kg (10 lb)
			<u>AS FOLLOW-UP TO POSITIVE ANALYSIS</u>		
Peanuts, roasted in shell (only for domestic runner variety)	Consumer or bulk	NA	<u>INITIAL SAMPLE</u>		
			15	454 gm (1 lb)	6.8 kg (15 lbs)
			<u>AS FOLLOW-UP TO POSITIVE ANALYSIS</u>		
Tree nuts (except in-shell Brazil Nuts and all pistachio nuts in import status) shelled, in-shell slices, pieces, or flour	Consumer or bulk	NA	<u>INITIAL SAMPLE</u>		
			10	454 gm (1 lb)	4.5 kg (10 lb)
			<u>AS FOLLOW-UP TO POSITIVE ANALYSIS</u>		
Tree nuts - paste			50	454 gm (1 lb)	22.7 kg (50 lbs)
			12	454 gm (1 lb)	5.4 kg (12 lbs)
Brazil Nuts in-shell (in import status)	Bulk	<200 bags	20	454 gm (1 lb)	9 kg(20 lbs)
		201-800"	40	"	18 kg (40 lbs)
		801-2000"	60	"	27 kg (60 lbs)
Pistachio nuts in-shell (in import status)	Bulk	multiples of 34,100 kg (75,000 lbs)	20 % of units	---	50 lbs for each multiple of 34,100 kg (75,000 lbs) or less
Pistachio nuts shelled (in import status)		SAME	SAME	---	25 lbs for each multiple of 34,100 kg (75,000 lbs) or less
Corn - shelled, meal flour or grits	Consumer or bulk	NA	10	454 gm (1 lb)	4.5 kg (10 lbs)
PRODUCT	PACKAGE TYPE	LOT SIZE	NUMBER OF SAMPLE	UNIT SIZE (minimum)	TOTAL SAMPLE SIZE (minimum)

UNITS*

Oil seed meals - Peanut meal, cottonseed meal	Bulk	NA	20	454 gm (1 lb)	9 kg (20 lbs)
Edible seeds** melon pumpkin, sesame, etc	Bulk	NA	INITIAL SAMPLE 10	454 gm (1 lb)	4.5 kg (10 lb)
			AS FOLLOW-UP TO POSITIVE ANALYSIS 50	454 gm (1 lb)	22.7 kg (50 lb)
Ginger Root dried whole	Bulk	"n" units	Sq root "n"	---	6.8 kg (15 lbs)
ground	Consumer	NA	16	16-28 gm (1 oz)	4.5 kg (10 lbs)
Milk - whole, skim low fat	Consumer	NA	10	454 gm (1 lb)	4.5 kg (10 lbs)
	Bulk	NA	---	---	4.5 kg (10 lbs)
Small grains - wheat sorghum, barley, etc	Bulk	NA	10	454 gm (1 lb)	4.5 kg (10 lbs)
Dried fruit** - e.g.: Figs	Consumer or bulk	NA	INITIAL SAMPLE 10	454 gm (1 lb)	4.5 kg (10 lb)
			AS FOLLOW-UP TO POSITIVE ANALYSIS 50	454 gm (1 lb)	22.7 kg (50 lb)
Mixtures containing commodities susceptible to mycotoxin contamination	Consumer	NA			
Commodity particles relatively large			50	454 gm (1 lb)	22.7 kg (50 lbs)
Commodity particles relatively small			10	454 gm (1 lb)	4.5 kg (10 lbs)

NOTE: Containers for samples of unprocessed, intact nuts, seeds, or grains must be sufficiently porous to provide for dissipation of moisture produced by respiration of the nut, seed, or grain.

* To be collected from as many random sites in the lot as possible. For surveillance samples, you may combine subs prior to shipping to the laboratory. For compliance samples, you must maintain sub integrity.

** Optional sampling program for seeds or dried fruit with a low incidence of contamination. Take initial 10 x 454 gm (1 lb) sample. If any aflatoxin is detected, resample 50 x 454 gm (1 lb) sample for determination of contamination level on which to base regulatory judgement.

CANNED FRUIT - FILL OF CONTAINER - AUTHENTIC PACK

Collect samples only on a specific assignment or during inspections when it appears that the firm is not filling the containers to capacity.

A. INVESTIGATIONAL SAMPLES: Authentic Pack Preparation.

Procedure for preparing authentic factory packs.

1. Remove 72 cans, 3 at a time, from packing line after fruit has been added and before syruing.
2. Mark 24 cans with the sub numbers A-1, A-2, A-3, etc.; 24 cans with sub numbers B-1, B-2, B-3; and 24 cans with sub numbers C-1, C-2, C-3, etc. See IOM 451.3.
3. Drain water from the "B" subs by inverting each can for 10 seconds, holding the fruit so it doesn't fall out.
4. Obtain gross weight of each can and record data for each series of sub on 3 separate FDA-485 - Field Weight Sheets.
5. Add additional fruit of the same kind and style to the "C" subs until the cans are filled to capacity. **Do not** tamp the contents or crush the fruit.
6. Record the number of fruit pieces added where the size of the fruit makes the procedure reasonable. **Do not** make time consuming counts of small pieces of fruit or berries.
7. Obtain the gross weight of the "C" subs after additional fruit is added and record on "C" series Field Weight Sheet.
8. Return all 72 cans to the filling line for syruing, exhausting, sealing, etc. in normal cannery operation.
9. Remove cans after cooking and cooling.
10. Identify cans with a single INV Sample number.
11. Attach FDA-485 - Field Weight Sheets to C/R.

B. OFFICIAL SAMPLES

See Sample Schedule Chart 2 for sample size.

C. SPECIAL REPORTING AND PRECAUTIONS

1. Report coding of cans and shipping cases.
2. Obtain label specimen(s) for the slack filled products.
3. Report shipments made before the inspection or since previous inspection in the same canning season.
4. **Do not** prepare Authentic Factory Samples when the cannery is packing for USDA fill-of-container certification unless:
 - a. USDA inspection is not continuous.
 - b. USDA Certification is for quality only.
 - c. USDA recommendations for weights are not being followed.

D. SAMPLE SUBMISSION

Submit samples to your district's designated workplan servicing laboratory.

IMPORTS - COFFEE, DATES AND DATE MATERIAL

1. Coffee - Wharf Examination - Note: Wharf Examine a minimum of six bags of coffee beans regardless of lot size. If a significant number of defective beans or significant contamination is found during the examination of these six bags, continue the examination using the following schedule, which applies for both Wharf Examination and samples for laboratory analysis:

LOT SIZE	NO. BAGS TO BE SAMPLED
100 or less	6 bags
101-200	10 bags
201-1000	15 bags
over 1000	20 bags

Sample each bag with a trier, collecting 1/2 pt. of beans from the top and 1/2 pt. from the bottom of the bag. The total quantity of beans taken from each bag must be the same, since both wharf and laboratory examinations are to be performed on a composite sample of all beans collected.

Shake each sub on a #8 sieve nested in a pan. Dump the sifted beans from each sub into a bag of sufficient size to hold and permit mixing all of the subs collected from the lot. Composite the subs. Do not maintain individually.

(a) Macroscopic Filth

Examine the siftings for macroscopic filth (live and dead whole insects, excreta pellets, extraneous material and sweepings), reporting findings for each sub separately. See IOM 427.4.

Transfer macroscopic filth, including all sifted material to a second bag and submit to the laboratory for confirmation. If live insect infestation is encountered, fumigate the filth portion containing the insects and the composite coffee bean sample. Report fumigant on CR and FDA-525. The lot will be detained if a live insect infestation is encountered, however, proceed with the defect bean examination since the reconditioning process will depend on the results.

(b) Defect Bean Examination

Thoroughly mix the composite sample of coffee beans and remove three-hundred beans at random. Examine each individual bean visually (or at a 5X magnification) for insect tunneling and mold damage. Count as moldy only those beans with 1/4 or more of the surface being moldy. Note: Each district office has examples of the various types of reject beans.

(c) Accept the lot if twenty or less rejects are found and discard the sample. Report your wharf examination into FACTS; no Sample Collection Report is necessary.

(d) If twenty-one or more rejects are detected, return beans examined to the composite and submit to the laboratory. You may discontinue the examination when twenty-one rejects are detected.

When a sample is submitted to the laboratory, all wharf examination time is reported as a field exam in FACTS and the sample collection time is reported as an import sample collection. All necessary documents for an import sample collection must be completed.

2. Dates & Date Material - Filth

Sample according to the following schedule:

NUMBER OF SUBSAMPLES REQUIRED**

NO. CONTAINERS IN LOT*	WHOLE DATES	DATE MATERIAL
100 or less	3	4
101 - 600	8	6
601 - 1,200	14	8
1,201 - 2,000	26	10
2,001 - 2,800	36	12
2,801 - 6,000	44	14
6,001 - 9,600	56	16
9,601 - 15,000	68	18
Over 15,000	82	22

* Schedule is based upon unit containers weighing between twenty and one-hundred pounds. For containers exceeding one-hundred pounds each, consider as two or more containers. For example, a one-hundred and fifty pound container is considered as two containers; a three-hundred pound container as three containers, etc.

** Each subsample should consist of two-hundred to three-hundred dates or two pounds of date material.

(a) Identify each subsample separately. Each lot will be a separate sample.

(b) Do not sample jujubes as dates. These are usually labeled as Chinese Red Dates, Dried Red Dates, or Honey Dates. Jujubes are not considered to be misbranded when called Chinese Red Dates, etc., because of the long standing use of these names. Sample jujubes following the above schedule, except duplicate subs are not necessary.

(c) If live insects are noted, include these as part of the sample collected and report on the C.R. which subs contained the insects and how many insects, adult or larvae, were noted. If live infestation is noted, place all subs from the lot sampled in clear glass jars and fumigate. Report what the fumigant used on the FDA-525 and the C.R.

SAMPLING SCHEDULE FOR COLOR
CONTAINING PRODUCTS
COLOR ADDITIVES

The following schedule provides general guidance for collecting samples of foods and cosmetics to determine whether non-permitted colors are present, rather than to determine the actual level of a particular color. This schedule was developed with the assumption that color distribution in the lot will be homogeneous. In the case of heterogeneous products, your supervisor should contact Center for Food Safety and Applied Nutrition, Office of Field Programs, Division of Enforcement (HFS-605) to determine sample size.

Sample size given includes the 702(b) portion.

INDUSTRY CODE**SAMPLE SIZE**

(DO NOT COMMINGLE CODES)
 (Min. 225 gm (8 oz)/pkg Unless
 otherwise specified)

GRAIN AND BAKING

02	Whole grains, Milled Grain Products and Starch	2 retail packages
03	Bakery Products, Doughs, Bakery Mixes, and Icings	2 retail packages
04	Macaroni and Noodle Products	2 retail packages
05	Cereal Preparations Breakfast Foods	2 retail packages
07	Snack Food Items (Flour, Meal, or Vegetable Base)	2 retail packages

DAIRY

09	Milk, Butter, and Dried Milk Pdts	Liquid Pdts: 2 pts where possible Solid: 2 packages
12	Cheese and Cheese Products	2 retail packages
13	Ice Cream and Related Products	6 items per sample (If item is single serving; ie., cup, popsicle, bar, etc.) 2 pt containers where possible, or 1 quart or 1/2 gal
14	Filled Milk and Imitation Milk Products	2 pints

EGGS

15	Egg and Egg Pdts	2 dozen whole eggs (e.g. colored hard boiled Easter eggs) 2 retail pkg of egg pdts
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FISH

16	Fishery/Seafood Pdts	2 retail packages.
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Any collection of smoked salmon should be selective, based on inspectional evidence

MEAT & SIMULATED MEAT PRODUCTS

17	Meat, Meat Products and Poultry	2 retail packages
18	Vegetable Protein Pdts	2 retail packages

FRUIT, NUT AND VEGETABLE PRODUCTS

20-22	Fruit & Fruit Pdts	2 retail packages canned or glazed. 12 fresh fruit (e.g., oranges, etc.).
23	Nuts & Edible Seeds	2 retail packages
24-25	Vegetable & Vegetable Products	2 retail packages
26	Vegetable Oils & Olive Oil	Liquids - 2 pints Solids - 2 retail packages

DRESSINGS AND SPICES

27	Dressings & Condiments	2 retail packages
28	Spices, Flavors, & Salts	Extracts - 2 pints Solids - 2 retail packages

BEVERAGES

29	Soft Drinks & Waters	6 Retail Units (Cans, Bottles, Packets)
30	Beverage Bases, Concentrates, and Nectars	Liquids - 1 pint Solids (Powder mix, packets) – 6 Consumer Pkg Solids - 2/225 gm (8 oz) or larger containers
31	Coffee and Tea	2 retail packages
32	Alcoholic Beverages	2 pints or 1 quart

CONFECTIONS AND DESSERTS

33	Candy w/o chocolate, Candy Specialties, and Chewing Gum	2 retail packages
34	Chocolate & Cocoa Pdts	2 retail packages
35	Gelatin, Rennet, Pudding Mixes, & Pie Fillings	6 pkgs - smallest consumer size
36	Food Sweeteners (Nutritive)	2 pints

MULTIPLE FOODS, SOUPS, SALADS, BABY FOOD AND DIETARY

37	Multiple Food Dinners Gravies, Sauces and Specialties (Total	Single Serving Dinners, etc - 4 pkgs Two Consumer Pkgs when 1 pkg serves more than 2
38	Soups	Same as 37 Above
39	Prepared Salad Products	Same as 37 Above
40	Baby (Infant and Junior) Food Pdts	Sufficient retail pkgs to total at least 454 gm (1 lb) of food
41	Dietary Conventional Foods and Meal Replacements	Same as 37 Above

COLORS AND COSMETICS

50	Color Additives for Foods Drugs, and Cosmetics	<ol style="list-style-type: none"> 1. Straight Color 28 gm (1 oz) powder. 2. Color Mixtures 110 gms (4 oz) Liq, paste or powder. <p>If mixture contains over 50% pure dye, 55 gm (2 oz) is sufficient</p>
53	Cosmetics	<p>Four retail packages of the same lot code for each shade (color) in the product line, if the product is <u>strongly colored</u>. (e.g., Lipsticks, hair coloring products, eye mascara, eye liners, make up pencils of all types)</p> <p>Sufficient number of retail packages to equal 1 lb or 1 pt of sample if the product is <u>lightly colored</u>. (e.g., creams, lotions, shampoos, bath products, shaving preparations, and perfumes.)</p> <p>Note: Always collect a minimum of two retail units of each product.</p>

MISCELLANEOUS

Bulk Items (Any bulk food or cosmetic)	Dry - 454 gm (1 lb) Liquid - Min 36 fl oz
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DRUG SAMPLING SCHEDULES

(Does not include Antibiotic Preparations)

STERILITY TESTING VITAMINS, DEVICES, & DRUGS

Type of Product	Sample Size ¹	
	INV Sample ²	Official [702(b) & Check] ³
DRUGS	36	86
DEVICES	46	106

LEGEND:

1. Double sample size requirements when individual containers are 2 ml (2 gm) or smaller.
2. INV sample includes units (30 for Drugs & 40 for devices) for examination and 6 units for bacteriostasis.
3. Official Sample includes units (30 for drugs & 40 for devices) for examination, units (30-40) for check, 20 units for 702(b) and 6 for bacteriostasis.

Note: If a lot is aseptically filled into 200 finished units or less, sample no less than 10% of lot.

DISSOLUTION TEST - USP & NF

Unless directed otherwise by your assignment or supervisor, submit samples to your normal servicing laboratory.

SAMPLE SIZE

Collect a 200 tablet portion for drug potency analysis by the collecting district lab, plus a separate 100 tab portion to be split for dissolution testing

MICROBIOLOGICAL EXAMINATION OF DRUGS (Other than for Sterility)

PRODUCT	<u>MINIMUM SAMPLE SIZE</u> (Includes 702(b) portion)	
	<u>Sub Size</u>	<u>Nos. of Subdivisions</u>
Dosage Form Drugs (See #1 below), Bulk Drugs, or Raw Materials for Manufacturing	90 gm or 90 ml	10

SAMPLING INSTRUCTIONS

1. Contact the laboratory (which has microbiological testing capabilities) serving your district for sample size requirements before sampling dosage form drugs containing less than 3 grains, 200 mg, or 25% of the suspect ingredient.
2. Use aseptic technique when collecting samples from raw materials or bulk containers. Implements and sample containers used must be sterile. Submit controls. See IOM 446 thru 446.4.
3. Submit samples to the laboratory with microbiological testing capabilities which serves your district unless directed otherwise.

VITAMIN SAMPLING

VETERINARY PRODUCTS, FEEDS, & BY-PRODUCTS FOR ANIMAL FEEDS

A. GENERAL

This sampling schedule may be used as a guide in the collection of surveillance or compliance samples resulting from district assignments or as a follow-up to violative inspections and/or investigations. Before collecting follow-up samples to violative inspections or investigations, contact your supervisor since it may be necessary for your district to consult with the Atlanta Center for Nutrient Analysis (HFR-SE680) when unscheduled compliance sampling is contemplated.

B. SAMPLE PRODUCT, SIZE, & SPECIAL INSTRUCTIONS

Vitamin-mineral testing, sampling instructions and information. Sample size includes 702(b) portion.

Unless excessive cost is a factor, collect at least 3 intact containers from each lot or control number. When sampling from bulk lots, collect appropriate subs from a minimum of 3 different bulk containers in the lot.

DOSAGE FORM VITAMIN-MINERAL PREPARATIONS (Single/Multiple Ingredients)

PRODUCT	NO. SUBSAMPLES	MINIMUM TOTAL SAMPLE SIZE	REMARKS
Injectables	3 vials/amps	30 ml	Split samples for sterility testing (60 vials/amps)
Tabs/Caps	3 retail units	300 Tabs/Caps	Split sample for micro tests (10/50 tab/cap subs)
Liquids	3 retail units	4 fl. oz.	Split sample for micro tests (10/2 fl. oz. subs)
Powders	3 retail units	112 gm (4 oz)	Same as above

FEEDS & BY-PRODUCTS FOR ANIMAL FEEDS (Vitamin-Mineral Claims)

Vitamin A & D Concentrates, Supplements & (A&D feeding	3 retail units(1/2 gal or less)	3 lbs (1.4 kg) 3 pints	Limit samples to those products containing at least 800 units/g Vit A and/or 80 Feeds units/g Vit D
Vitamin B ₂ (Riboflavin) Concentrates, Supplements, & feeds	Same	Same	Limit samples to those products containing at least 20 mg/lb
Vitamin B ₁₂ (Cyanocobalamin) Concentrates, Supplements & feeds	Same	Same	Limit samples to those products containing at least 1 mg/lb
Multiple Vitamins Concentrates, Supplements, & feeds.	Same	Same	Limit samples to those products meeting vitamin levels listed above.

C. SAMPLE SUBMISSION

Submit all samples for Vitamin Potency analysis to the Atlanta Center for Nutrient Analysis (HFR-SE680).

Submit samples for filth analysis, microbiological examination, sterility, etc. to your district servicing laboratory.

MEDICATED ANIMAL FEEDS SAMPLING

1. Medicated Premixes

A. Investigational Samples (INV Samples)

To demonstrate suspected drug carryover or other chemical contamination during manufacturing, collect 1-900 gm (2 lbs) of static residual material in the equipment, and the finished product premixes.

B. Official Physical Samples 702(b) Portion Included

For expensive premixes or components, collect a total of 3/170 gm (6 oz) subs; One sub from each of 3 containers. In the case of premixes packaged in plastic, e.g., mini-packs, follow instructions under bagged premixes.

1. Bagged Premixes

Collect 10 - 454 gm (1 lb) subs from each lot. Sample all bags in lots under 10 bags, for a total of 10 subs from the lot.

Collect 454 gm (1 lb) subs from at least 10 different bags selected at random in lots of more than 10 bags.

2. Bulk Premixes

Collect at least 10 - 454 gm (1 lb) subs, from different locations in the lot providing a minimum total sample of 4.5 Kg (10 lbs).

C. Documentary Samples (DOC Sample) - Refer to IOM 405.12 for guidance on the collection of DOC Samples.

II. Medicated Feeds

A. Investigational Samples (INV Sample)

Collect 1 - 900 gm (2 lb) of static residual material in the equipment and correlate with finished feed samples to show that residues are being carried over into the finished product.

B. Official Samples (Includes 702(b) portion)

1. Bagged Complete Feed

Collect a total sample of not less than 2.3 Kg (5 lbs) from each lot. Collect 454 gm (1 lb) subs sampling all available bags from lots of 10 bags or less. If lot size is greater than 10 bags, collect 454 gm (1 lb) from each of 10 bags selected at random.

2. Bulk Complete Feed

Collect at least 10 - 454 (1lb) subs from different points in the bulk lot to obtain a minimum total sample of 4.5 kg (10 lbs).

3. Concentrates/Supplements

If the concentrate or supplement is relatively inexpensive, follow the sampling procedures for complete feeds. Limit sampling of more expensive drug materials, concentrates, or supplements to no more than 3 containers taking a 170 gm (6 oz) or 6 fl. oz. sub from each of the 3 containers.

C. Documentary Samples (DOC Sample)

1. Feed Subject to MFA Approval - Collect DOC Samples of products processed without required MFA approval. Where the plant does not ship in IS commerce, but ingredients are received from IS sources, document the IS nature of drug ingredients and the "Held For Sale" status of the finished feed. Labeling of drug ingredients must be submitted.

2. Misbranded Products - Collect a DOC Sample for misbranding or labeling deficiencies. The failure to provide warning and/or withdrawal statements which could present danger to animals or man, or gross evidence of false and misleading therapeutic claims, are factors for consideration.

III. Sampling Precautions (See IOM CHART 4)

A. Insert the trier the full length of the bag when sampling bagged premixes, or complete feeds.

B. Clean trier between sampling the different lots of premixes or complete feeds.

C. Place subs in clean airtight container, preferably clean glass jars.

D. DO not fumigate samples intended for potency analysis, drug carryover or cross-contamination.

IV. Sample Submission

Submit samples to your district's servicing laboratory or as directed by your assignment or supervisor. See IOM 454.2.

